PATENT Case No. MC060P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Billot et al

10/521,508 Serial No. 09/626.699

Filed: January 18, 2005

For: EP4 Receptor Agonist, Compositions and Methods Thereof

Art Unit: To be Assigned

Examiner:

To be Assigned

Commissioner for Patents P.O. Box 1450 , Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- 4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. on the date appearing below.

MERCK & CO., INC.

ter generated form "IDS Latter" (IDS Folder), Marck & Co., Inc., 02/09/2005

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application refies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

	RELATED APPLICATION				
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE			
		 			
		 			

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1,97, (check one)

V	the attached information is filed within three months of the filing date of the captioned case.
\Box	the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
	the attached information is being flied more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
	the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
	the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.50(c) more than three months prior to the filing of this Statement.
	By: Sylvia A Aylg Attorney For Applicant(s)
	Reg. No. 38,436 MERCK & CO., INC. Patent Dept., RY60-30 P.O. Box 2000 Rahway, N.J. 07065-0907 (732)594-4909 Date: April B. 2005
	Date: April 8, 2005

					SUBSTITUTE	or PTO/SB/08A (03-03). Information Disclosure Statement by Applicant Pages and Trademork Office; U.S DEPARTMENT OF COMMERCE
(s	ubstitute for form 1449A/PTO		,		COMPLETE IF KNOWN
	313	NFORMATION	DIS	CLOSURE	Application Number	091626.999 10/521.508
1		TATEMENT BY	7 A TO	DICANT	Filing Date	January 18, 2005
	R 1 1	700	AI	FLICANI	First Named Inventor	Billot et al.
		AF		,	Group Art Unit	To be Assigned
% \	(use as many sheets a			iecessary)	Examiner Name	To be Assigned
	Sheet	1	of	5	Attorney Docket Number	MC060P
•	_					

		U.	S. PA	TENT DOCUMENTS		
Examiner Initials*	Cite No.			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	
	1.	4,386,098		Woltersdorf Jr. et al.	05/31/1983	
	2.	4,416,890		Woltersdorf Jr. et al.	11/22/1983	
	3.	4,426,388		Woltersdorf Jr. et al.	01/17/1984	
	4.	4,668,697		Shepard et al.	05/26/1987	
	5.	4,863,922		Baldwin et al.	09/05/1989	
	6.	4,797,413		Baldwin et al.	01/10/1989	
	7.	5,378,703		Dean et al.	01/03/1995	
	8.	5,240,923		Dean et al.	08/31/1993	
	9.	5,153,192		Dean et al.	10/06/1992	
	10.	4,883,819		Bito	11/28/1989	
	11.	4,824,857		Goh et al.	04/25/1989	
	12.	5,001,153		Ueno et al.	03/19/1991	
	13.	4,599,353		Bito	07/08/1986	
	14.	6,043,275		Maruyama et al.	03/28/2000	
	15.	5,698,598		Woodward	12/16/1997	
	16.	5,462,968		Woodward	10/31/1995	
	17.	6,344,477		Sharif	02/05/2002	
	18.	5,889,052		Klimko et al.	03/30/1999	
	19.	5,296,504		Stjernschantz et al.	03/22/1994	
	20.	5,422,368		Stjernschantz et al.	06/06/1995	

	_	_			DOCUMENTS	
Examiner Initials*			Foreign Patent Docume Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	21.	PCT	WO 00/38667		Alcon Laboratories	07/06/2000
22. PCT WO 99/32441		AI	Alcon Laboratories	07/01/1999		
	23. PCT WO 99/02165		Al	Pharmacia & Upjohn Ab	01/21/1999	
	24.	PCT	WO 00/38663	A2	Alcon Laboratories	07/06/2000
	25.	PCT	WO 01/46140	Al	Pfizer Products Inc.	06/28/2001
	26.	EP	EP 0855389	A2	Ono Pharmaceutical Co., Ltd.	01/26/1998
	27.	JP	JP 2000-1472			01/07/2000
	28.	PCT	WO 00/38690	A2	Alcon Laboratories, Inc.	07/06/2000
	29.	PCT	WO 02/ 24647	Al	Ono Pharmaceutical Co., Ltd.	03/28/2002
	30.	PCT	WO 02/42268	A2	Pfizer Products Inc.	05/30/2002
Examin Signatur	er re				Date Considered	

Examine: Initial If reference considered, whether or not classion is in conformance with NPEP 609. Draw line through classion if not in conformance and not considered. Include copy of the notion of the communication angularity of the notion of the communication of the conformance and not considered. Include copy of the notion of the not

			SUBSTITUTE R	PTO/SBUSA (08-03). Information Disclosure Statement by Applicant Patent and Trudemurk Office; U.S DEPARTMENT OF COMMERCE
stitute for form 1449A/PTO				COMPLETE IF KNOWN
FORMATION	N DISC	LOSURE	Application Number	091626,699 10/521, 508
CANCAGENT D	W A DD	ICANT	Filing Date	January 18, 2005
@1	IAFF	LICANI	First Named Inventor	Billot et al.
<i>§</i>			Group Art Unit	To be Assigned
(use as many sne	eis as nec	essary)	Examiner Name	To be Assigned
_ 2	of	5	Attorney Docket Number	MC060P
	rågement b 13	FORMATION DISC FATEMENT BY APP 15 (use as many sheets as nec	ATEMENT BY APPLICANT [15] [(ukl as many sheets as necessary)	FORMATION DISCLOSURE Application Number Filing Date First Named Inventor Group Art Unit Examiner Name

	_	U.S. Patent Document	U.U. I /	TENT DOCUMENTS	
Examiner Initials*	Cite No.	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	31.	5,151,444		Ueno et al.	09/29/1992
	32.	5,352,708		Woodward et al.	10/04/1994
	33.	4,690,931		Wick et al.	09/01/1987
	34.	4,970,335		Isomura et al.	11/13/1990
	35.	5,296,504		Stjernschantz et al.	03/22/1994
	36.	5,422,368		Stjernschantz et al.	06/06/1995
	37.	5,510,517		Dauer et al.	04/23/1996
	38.	5,648,491		Dauer et al.	07/15/1997
	39.	4,922,007		Kiecykowski et al.	05/01/1990
	40.	5019651		Kiecykowski et al.	05/28/1991
	41.	4927814		Gall et al.	05/22/1990
•					
\neg					
				-	

			Foreign Patent Documer	ıt		Date of Publication of
Examiner Initials*	Cite No.	Office	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY
	42.	EP	EP 1132086	A2	Pfizer Products Inc.	01/31/2000
	43.	43. EP EP 1114816 A		AI	Ono Pharmaceutical	09/10/1999
	44. PCT WO 01/72268 A1		Al	Toray Industries	03/30/2001	
	45.	PCT	WO 94/13275	Al	Massachusetts Eye and Ear Infirmary	06/23/1994
	46.	PCT	WO 01/70702	Al	Alcon Universal Ltd.	09/27/2001
	47.	PCT	WO 02/077168	A2	Merck & Co. Inc.	10/03/2002
	48.	PCT	WO 02/060863	Al	Merck & Co. Inc.	01/30/2001 04/20/2000 10/24/2001
	49.	PCT	WO 00/21542	Al	Merck & Co. Inc.	
	50.	EP	EP 0561 073	Bl	R-Tech Ueno Ltd.	
	51.	PCT	GB 1 487 842		Hoechst Aktiengesellschaft	10/05/1977

*Eastine: Initial II reference considered, whether or not cluston is in confarence with MPEP 609. Draw line through cluston if not in confarence and not considered. Include copy of this form with rest communication to applicate.

SEND TO: Compare generated sens 1005 from* (IDS Febric & Co., Inc., 0000000)

SEND TO: Compare generated sens 1005 from* (IDS Febric & Co., Inc., 0000000)

use through 7/31/2006. CMB 0631-0031

	•	SUBSTITUTE &	PTO/SB/08A (03-03), Information Darkouse Statement by Applicant Parest and Trademark Office; U.S DEPARTMENT OF COMMERCE	
1	Substitute for form 1449A/PTO	COMPLETE IF KNOWN		
١	INFORMATION DISCLOSURE	Application Number	091626,999 10/521,508	
ı	STATEMENT BY APPLICANT	Filing Date	January 18, 2005	
Λ	STATEMENT BY AFFEICANT	First Named Inventor	Billot et al.	
3	APR 1 1 2005 (1)	Group Art Unit	To be Assigned	
P	č	Examiner Name	To be Assigned	
(Sheer and 3 of 5	Attorney Docket Number	MC060P	

U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No.	U.S. Patent Docum Number		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY			
		3-						

			FOREI	GN PATE	NT DOCUMENTS	
Examiner Initials*	Cite No.	Offic	Foreign Patent Documents Number	King Cod	of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	52.	JР	WO 03/009872		Ono Pharmaceutical Co.	07/22/2002
	53.	JP	WO 03/074483		Ono Pharmaceutical Co.	09/12/2003
		L				
	_	L				
		<u> </u>				
		<u> </u>				
	<u> </u>	<u> </u>				
		<u> </u>				
					<u> </u>	
Examin Signatur	er				Date Considered	

Approved for one through 7/31/2006. OMB 0651-0031 SUBSTITUTE for PTO/SB/08A (08-03), Information Disclosure Summers by Applicant

				30001110121	Potent and Trademark Office; U.S DEPARTMENT OF COMMERCE
<i>(</i> ,	Substitute for form 1449B/PTO				COMPLETE IF KNOWN
	INFORMATION	DIS	CLOSURE	Application Number	09/626,999 10/521.508
0	STATEMENT BY	7 A 101	DITCANT	Filing Date	January 18, 2005
1 '	SIAILERI BI	Ar	FLICANI	First Named Inventor	Billot et al.
APR '	1 1 2005			Group Art Unit	To be Assigned
B	(use as many sheet	s as n	ecessary)	Examiner Name	To be Assigned
Sheet	-narist 4	of	5	Attorney Docket Number	MC060P
_					

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.			
	54.	A. Ichikawa et al., "Molecular Aspects of the Structures and Functions of the Prostaglandin E. Receptors", 1996, pp. 83-87, Vol. 14, J. Lipid Mediators Cell Signaling.			
	55.	A. J. Flach et al., "Topical Prostaglandin EZ Effects on Normal Human Intraocular Pressure", 1988, pp. 13-18, Vol. 4, J. Ocular Pharmacology.			
	56.	D. F. Woodward et al., "Molecular Characterization and Ocular Hypotensive Properties of the Prostqanoid EP2 Receptor", 1995, pp.447-454, Vol. 11, No. 3, J. Ocular Pharmacology.			
	57.	D. F. Woodward et al., "Intraocular Pressure Effects of Selective Prostanoid Receptor Agonists Involve Different Receptor Subtypes According to Radioligand Binding Studies", 1993, pp. 545-553, Vol. 6, J. Lipid Mediators.			
	58.	L. D. Waterbury et al., "EP3, but Not EP2, FP, or TP Prostanoid-Receptor Stimulation May Reducse Intraocular Pressure", 1990, pp. 2560-2567, Vol. 31, No. 12, Investigative Ophthalmology and Visual Science.			
	59.	E. M. Ross, "Mechanisms of Drug Action and the Relationship Between Drug Concentration and Effects" 1996, Chapter 2, The Pharmacological Basis of Therapeutics.			
	60.	M. A. Lemp, "Report of the National Eye Institute/Industry Workshop on Cinical Trials in Dry Eyes", 1995, pp. 221-231, Vol. 21, No. 4, The CLAO Journal.			
	61.	I.K. Gipson et al., "Mucin Genes Expressed by the Ocular Surface Epithelium", 1997, pp. 81-98, Vol. 16, Progess in Retinal and Eye Research.			
	62.	D. A. Dartt et al., "Localization of Nerves Adjacent to Goblet Cells in Rat Conjucntiva", 1995, pp. 993-1000, Vol. 14, Current Eye Research.			
	63.	R. A. Schumer et al., "The Nerve of Glaucoma!", 1994, pp. 37-44, Vol. 112, Arch. Ophthalmol.			
	64.	L. Dandona et al., "Selective Effects of Experimental Glaucoma on Axonal Transport by Retinal Ganglion Cells to the Dorsal Lateral Ceniculate Nucleus", 1991, pp. 1593-99, Vol. 32, No. 5, Investigative Ophthalmol. & Visual Science.			
	65.	Ikeda et al., "In Situ Localization of Three Subtypes (EP_1, EP_3 and EP_4) of Prostaglandin E Receptors in Embryonic and Newborn Mice", 1995, Vol. S172, J. Bone Miner Res.			
	66.	Rodan et al., "Growth Stimulation of Rat Calvaria Osteobalstic Cells by Acidic FGF",1987, pp. 1919-1923, Vol. 121, Endocrinology.			
	67.	Samulesson et al., 1995, pp. 499-504, Vol. 23, Advances in Prostaglanding Thrombosznes and Leukotriene Research.			
	68.	DeLarco et al., "Epithelioid and Fibroblastic Rat Kidney Cell Clones: EGF Receoptros and the Effect of Mouse Sarcoma Virus Transformation", 1978, pp. 335-342, Cell Physiol.			

Signature	The state of the s	Considered	J			
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy						

Approved for use through 7/31/2006. OMB 0651-0031 SUBSTITUTE for PTO/SB/08A (08-03), Information Disclosure Statement by Applicant

٠				SUBSTITUTE	or PTO/SB/08A (08-03), Information Disclosure Statement by Applicant Putent and Trademark Office; U.S DEPARTMENT OF COMMERCE	
Substitute for form 1449SPTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT APR 1 1 7075				COMPLETE IF KNOWN		
				Application Number	09/626,999 10/521,508	
				Filing Date	January 18, 2005	
				First Named Inventor	Billot et al.	
1				Group Art Unit	To be Assigned	
(use as many sheets as necessary)				Examiner Name	To be Assigned	
She	et 5	of	5	Attorney Docket Number	MC060P	
=		_				

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.			
	69.	M. Abramovitz et al., "The Utilization of Recombinant Prostanoid Receptors to Determine the Affinities and Selectivities of Prostaglandins and Related Analogs", 2000, pp. 285-293, Vol. 1483, No. 2, Biochim Biophys Acta.			
	70.	Chomczynski et al., "Signal-Step Method of RNA Isolation by Acid Guanidium Thiocyanate-Phenol-Chloroform Extraction", 1987, pp. 156-159, Vol. 162, Analyt Biochem.			
	71.	Weinreb et al., "Different Pattern of alkaline Phosphatase, Osteopontin and Osteocalcin Expression in Developing Rat Bone Visualized by In-Sittu Hybridization", 1990, pp. 831-842, Vol. 5, J. Bone Miner Res.			
	72.	D. Shinar et al., "Expression of Alphav and Beta3 Integrin Subunits in Rat Osteoclasts in Situ", 1993, pp. 403-414, Vol. 8, J. Bone Miner. Res.			
	73.	M. P. Sibi et al., "A New Electrophilic Alaninol Synthon. A General Route to Ozazolidinones of D or (R)-2-Amino Alcohols from L-Serine", 1994, pp. 1675-1678, Chem. Soc. Perkin Trans.			
•	74.	T. Ishizuka et al., "Mild and Selective Ring-Cleavage of Cyclic Carbamates to Amino Alcohols", 1987, pp. 4185-4188, Vol. 28, No. 36, Tetrahedron Letters.			
	75.	O.T. Quimby et al., "Tetrasodium Carbonyldiphosphonate. Synthesis, Reactions, and Spectral Properties", 1967, pp. 41114114, Vol. 32, J. Org. Chem.			
	76.	Matsunaga, "Novel Prostaglandin Derivative", Patent Abstracts of Japan, Vol. 007, No. 268 & JP 58 150575.			
		-			

Examiner Signature	Date Considered					
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with part comparison in a conformance and not considered.						